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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,754	11/22/2000	Kathryn K. Lappegard	1189	3443

27310 7590 05/06/2005

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EXAMINER

BAUM, STUART F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/718,754	Applicant(s) LAPPEGARD ET AL.	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,21,41,44 and 45 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 1,21,44 and 45 is/are rejected.
- 7) ☒ Claim(s) 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/20/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 1/24/2005 has been entered.
2. Claims 1, 6, 21, 41 and 44-45 are pending and are examined in the present office action.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Written Description

5. Claims 1, 21 and 44-45 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/28/2004. Applicant's arguments filed 1/24/2005 have been fully considered but they are not persuasive.

Applicants contend that supporting arguments previously submitted in the amendments filed August 8, 2003 and April 19, 2004 are maintained (page 6, 3rd paragraph).

The office contends that responses to Applicants' arguments previously submitted on 10/20/2003 and 7/28/2004 are maintained.

Applicants contend that functional cis-acting elements responsible for seed-preferred expression were well known in the art at the time of filing. Applicants contend that by disclosing identifying characteristics such as transcription initiation sites and expression patterns as determined by Northern blot, evidence has been provided that Applicant was in possession of the claimed invention (page 6, 3rd paragraph).

Art Unit: 1638

The Office requires that Applicants demonstrate that they are in possession of their claimed invention. In the instant application, Applicants' broadest claims are drawn to any promoter fragment of SEQ ID NO:1. In order to meet the test set forth in *Eli Lilly*, Applicants are required to disclose a representative number of promoter sequences to define the genus of promoters of SEQ ID NO:1, or Applicants are to disclose the structural features common to their genus of promoter sequences comprising fragments of SEQ ID NO:1. Applicants fail on both counts. Moreover, Applicants fail to draw the nexus between structure and function that defines their claimed genus of promoter fragments. Applicants are claiming a promoter fragment comprising any number of nucleotides of SEQ ID NO:1, but Applicants have not presented by way of disclosure or example, a single promoter fragment of SEQ ID NO:1, whose promoter activity is the same as the promoter activity of the nucleotide sequence of SEQ ID NO:1. Because Applicants have not disclosed a representative number of promoter sequences, structural features common to the genus of fragments of the promoter sequence of SEQ ID NO:1, Applicants are not in possession of the broadly claimed invention. In addition, the Office contends that Applicants' disclosure of SEQ ID NO:1 does not fulfill the written description requirement for claims drawn to any promoter fragment of SEQ ID NO:1. Applicants have not disclosed which fragments have the necessary structural features common to all promoters of the genus of promoters of SEQ ID NO:1. Applicants only describe a single promoter of SEQ ID NO:1. Without this information, Applicants have not fulfilled the written description requirement for claims drawn to fragments of SEQ ID NO:1.

Enablement

6. Claims 1, 21 and 44-45 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 7/28/2004. Applicant's arguments filed 1/24/2005 have been fully considered but they are not persuasive.

Applicants assert it was readily accepted in the art at the time of filing that the expression profile of a coding region as determined by Northern analysis is positively correlated with the expression pattern of the isolated promoter (page 7, 1st full paragraph).

The Office contends that the Northern analysis reflects the endogenous expression of a gene. In the instant case, Applicants have isolated a nucleic acid that presumably directs expression of a coding region in a manner that mimics the endogenous expression of the gene from which the promoter was isolated. It is well known in the art that promoter sequences do not contain 5' motifs that specify the 5' end of the promoter. The Office contends that Applicants have not disclosed information correlating the isolated nucleic acid molecule of SEQ ID NO: 1 with any expression data, other than the Northern analysis of the endogenous gene. Given the lack of expression data, it would not be clear to one of skill in the art, if the isolated promoter of SEQ ID NO: 1 actually directs expression as is observed for the endogenous gene.

Applicants contend that supporting arguments previously submitted in the amendments filed August 8, 2003 and April 19, 2004 are maintained (page 8, 1st paragraph).

Art Unit: 1638

The office contends that responses to Applicants' arguments previously submitted on 10/20/2003 and 7/28/2004 are maintained.

Applicants contend that screening panels or libraries containing from a few to many inoperative species in order to isolate one or more operative species is a common practice in many aspects of the biotechnological arts. Applicants contend that the isolation of operative Jip1 promoter fragments from a panel or library of candidate promoter fragments is not undue experimentation where the Examiner has not put forth any evidence that the number of inoperative species would be significant, where temporal and spatial expression motifs are known in the art (page 8, bottom paragraph).

The Office contends that Applicants are responsible for teaching one skilled in the art how to make and/or use the claimed invention without undue experimentation. For claims drawn to fragments of SEQ ID NO:1, Applicants are not enabled because Applicants have not taught which fragment of SEQ ID NO:1 has the claimed promoter function. For one skilled in the art, undue experimentation would be required to isolate and screen through the myriad of fragments of SEQ ID NO:1, to verify those that have the claimed seed preferred promoter function. To isolate each fragment of SEQ ID NO:1, one skilled in the art first has to design primers to be used in a PCR reaction to amplify any fragment sequence. Given that the promoter is 1247 base pairs long, there are thousands of different sequences. To amplify each and every one, requires that corresponding pairs of primers be designed and used in PCR reactions. Once a fragment is produced, it has to be isolated and sequenced to ensure that no mistakes were introduced during the PCR reaction. Once verified, the fragment is subcloned into a vector for further molecular manipulations which ultimately produce an expression construct comprising the specific

Art Unit: 1638

fragment of SEQ ID NO:1 operably linked to a reporter gene. This expression construct is further subcloned into a binary vector that is used to either transform *Agrobacterium* which is ultimately used to transform any plant explants, or the binary vector is used in another method of plant transformation, e.g., biolistic transformation. Transformed explants/callus/plants are selected on petri plates containing a selection medium or are selected as plants using a selectable marker. The transgenic explants/callus/plants are tested via PCR or Southern analysis for the intended construct. For a proper analysis, individual transformed plants are crossed to wild-type plants, and then the progeny F1 seeds are harvested and then subsequently grown and selected again, to identify those plants with the intended promoter construct. From each cross, a minimum of 20 plants have to be tested because of Mendelian Segregation, i.e., only one out of four plants will carry the promoter construct. For one promoter construct, 400 plants have to be grown and analyzed for proper promoter activity. This would have to be repeated to test each possible fragment. In the end, tens of thousands of plants have to be tested.

Applicants contend that temporal and spatial expression motifs are known, but these motifs are not for all plants. Applicants' claims are drawn to seed-preferred expression but Applicants have not specified in which plant. Seed-preferred expression motifs that are required for corn, are not necessarily required for seed-preferred expression in legumes. Given the lack of disclosure, undue trial and error experimentation would be required by one of skill in the art to practice the claimed invention.

7. SEQ ID NO:1 is deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1.

Art Unit: 1638

8. Claim 41 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claim 6 is allowable.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

Art Unit: 1638

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
April 26, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", written in a cursive style.